

## Biotechnology-related Business as the Growth Field of the Future

### 5-ALA Related Business (SBI Pharmaceuticals/SBI ALApromo)

The SBI Group, focusing on the possibilities of 5-ALA (5-aminolevulinic acid) for the human body, established SBI ALApromo (currently SBI Pharmaceuticals) in April 2008, for the purpose of finding applications for 5-ALA in medicines. The health foods and cosmetics that use 5-ALA are sold by SBI ALApromo as before. These health foods and cosmetics have already been well received. The Monde Selection 2012, for example, awarded NatuALA-Bio and NatuALA-BCAA the gold prize in its food supplements category, and ALAplus Essential Lotion and ALAplus Moisturizing Cream the silver prize in its facial products category.

#### • Medical Field Research, Development and Overseas Expansion

Along with the 5-ALA research, development and commercialization in health foods and cosmetics, progressive research is being conducted into the pharmaceutical potential of 5-ALA.

medac GmbH, a German business partner of SBI Pharmaceuticals, obtained approval from the European Medicines Agency (EMA) for a brain tumor diagnostic agent containing 5-ALA, and has already marketed the agent in 27 European countries. The diagnostic agent also received orphan drug designation in Japan in September 2010, and in July 2012 an application was made to the Japanese Ministry of Health, Labour and Welfare, for manufacturing and marketing approval for the agent. In addition, clinical trials to be carried out in several fields, are about to get underway in Japan, the United States and Europe in partnership with a Contract Research Organization (CRO) abroad.

The research is conducted in a wide range of fields. The University of Hawaii published the results of clinical studies on the relationship between 5-ALA and glucose levels in June 2012. 5-ALA has become a major focus of attention, with potential other applications being investigated in several fields, such as the suppression of accumulation of body fat in an experiment with cells and animals, antiproliferative effect for the malaria parasite, and



the suppression of inflammatory cytokine which can be a direct fatal cause of sepsis.

Moreover, in April 2012 SBI Pharmaceuticals reached a basic agreement for a close partnership with the government of Bahrain, to promote 5-ALA related research and development in Bahrain and other states of the Gulf Cooperation Council (GCC), and to proliferate its use throughout the region. A license to manufacture and sell health foods in Bahrain was granted by the Ministry of Health of the Kingdom of Bahrain, and preparations are underway to register the product throughout the entire GCC region.

Overseas expansion is also taking place in the Philippines, where in January 2012 a health food product registration certificate was granted by the Food and Drug Administration (FDA) of the Philippines. Preparations for product launch in the Philippines are now underway, in collaboration with local firms. In China, a basic agreement was reached in June 2012 with SuZhou YiAn Biotech Co., Ltd., in which the SBI Group will invest, to establish a joint venture for the purpose of marketing medicines, health foods and cosmetics containing 5-ALA.

#### What is 5-ALA (5-aminolevulinic acid)?

5-ALA is an amino acid formed in mitochondria. It is an important substance that serves as protein material related to energy production in the form of hemes and cytochromes. 5-ALA is contained in shochu distillation remnants, red wine and food, such as radish sprouts. It is also known as a material forming chloroplasts in plants.

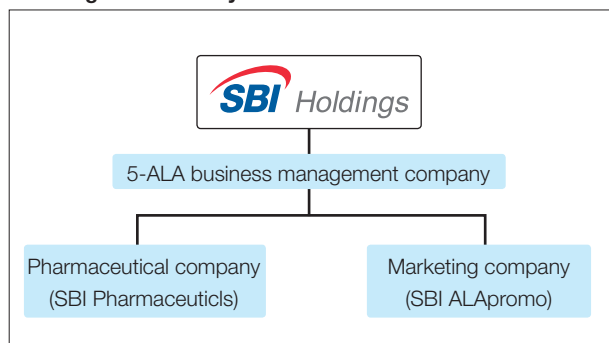
The SBI Group regards biotechnology as a next-generation core industry. In addition to our biotechnology investments, the SBI Group has been engaged in biotechnology-related businesses through the operations of SBI Pharmaceuticals, SBI ALApromo and SBI Biotech.

The Biotechnology-related Business is regarded as one of the three core business segments of the SBI Group, with the 5-ALA related business in particular positioned as its most promising growth area, and we are moving ahead with global development in cosmetics, health foods, and drug discoveries.

#### • New Organizational Structure for 5-ALA Related Business

In February 2012, following the completion of Phase III clinical testing for an intraoperative diagnostic agent for brain tumors, in consideration of the possibility that this agent might be approved as a drug, the former SBI ALApromo obtained a license to manufacture and sell Class 1 Over-The-Counter (OTC) drugs. In April 2012, the former SBI ALApromo took the opportunity to change its corporate name to SBI Pharmaceuticals Co., Ltd., to become a pharmaceutical company for research and development of medicines, etc. Meanwhile, the new SBI ALApromo was established as a marketing company for supplements and cosmetics. With the sales and production businesses thus separated, the new organizational structure allows independent focus by SBI Pharmaceuticals and SBI ALApromo on their respective businesses. Under the new organizational structure, the SBI Group will dedicate itself to further expanding 5-ALA related business through vigorous promotion of its overseas operations, to become one pillar of the Group's profitability.

#### New Organizational System for the 5-ALA Related Business



#### SBI Biotech

SBI Biotech is a bio-venture founded with Dr. Kenichi Arai (professor emeritus of the University of Tokyo, and former Dean of the Institute of Medical Science, University of Tokyo) as its President and CEO. The company is primarily engaged in the research and development of novel drugs for cancer, autoimmune diseases, etc.

SBI Biotech has formed business alliances with overseas bio-ventures and research institutes, which provides advantages

in implementing its current projects.

For example, in the field of immunomodulator therapy (nucleotide drugs), SBI Biotech has partnered with Changchun Huapu Biotechnology Co. Ltd., a drug development venture originating at the Jilin University, China, to conduct Phase I clinical trials at a number of U.S. universities. In the same field, SBI Biotech is also gearing up for joint clinical studies after a request from a North American medical practitioners' group for treatment of acute childhood leukemia. In the field of immune cell therapy, SBI Biotech has an agreement with Baylor Research Institute of the United States, under which it is conducting Phase II clinical trials in patients with melanoma in the United States. Meanwhile, in Japan, SBI Biotech began clinical trials at Kyoto University Hospital in July 2011.

At the same time, SBI Biotech is pursuing internal R&D projects into antibodies for cancer and autoimmune diseases. For one research project, SBI Biotech has aligned itself with MedImmune LLC of the United States (part of the AstraZeneca Group), while in another project it is negotiating tie-ups with leading domestic and overseas pharmaceutical companies. SBI Biotech is also working on the development of a novel cancer therapy, and in April 2010 filed an international patent application for research in partnership with CrystalGenomics, Inc. of South Korea.

#### Biotechnology-related Investee Companies

Drug research and development at biotechnology-related investee companies of the SBI Group is also progressing steadily.

Acucela Inc. of the United States, in which the SBI Group has had a stake since October 2003, with a 15.27% (dilutive shares included: 21.80%) shareholding as of the end of March 2012, performs drug development research in applications for the patented visual cycle modulators (VCM). Drugs for dry advanced macular degeneration (Dry AMD) using VCM compounds received fast track designation from the U.S. FDA in March 2010, and have become a focus of media attention, including that of Nikkei Business Magazine.

The SBI Group has also acquired a 16.8% shareholding (as of the end of December 2011) in Kadmon Holdings, LLC of the United States. Kadmon has already started selling treatment drugs for hepatitis C, and has steadily progressed to the clinical trial stage with research and development it has done on drug treatments for liver disease and tumors.